

§ 26.12

21 CFR Ch. I (4–1–01 Edition)

§ 26.12 Nature of recognition of inspection reports.

(a) Inspection reports (containing information as established under § 26.8), including a good manufacturing practice (GMP) compliance assessment, prepared by authorities listed as equivalent, will be provided to the authority of the importing party. Based on the determination of equivalence in light of the experience gained, these inspection reports will normally be endorsed by the authority of the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in an inspection report, quality defects identified in the postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the authority of the importing party may request clarification from the authority of the exporting party which may lead to a request for reinspection. The authorities will endeavor to respond to requests for clarification in a timely manner.

(b) Where divergence is not clarified in this process, an authority of the importing country may carry out an inspection of the production facility.

§ 26.13 Transmission of postapproval inspection reports.

Postapproval good manufacturing practice (GMP) inspection reports concerning products covered by this subpart will be transmitted to the authority of the importing country within 60-calendar days of the request. Should a new inspection be needed, the inspection report will be transmitted within 90-calendar days of the request.

§ 26.14 Transmission of preapproval inspection reports.

(a) A preliminary notification that an inspection may have to take place will be made as soon as possible.

(b) Within 15-calendar days, the relevant authority will acknowledge receipt of the request and confirm its ability to carry out the inspection. In the European Community (EC), requests will be sent directly to the relevant authority, with a copy to the Eu-

ropean Agency for the Evaluation of Medicinal Products (EMA). If the authority receiving the request cannot carry out the inspection as requested, the requesting authority shall have the right to conduct the inspection.

(c) Reports of preapproval inspections will be sent within 45-calendar days of the request that transmitted the appropriate information and detailed the precise issues to be addressed during the inspection. A shorter time may be necessary in exceptional cases and these will be described in the request.

§ 26.15 Monitoring continued equivalence.

Monitoring activities for the purpose of maintaining equivalence shall include review of the exchange of inspection reports and their quality and timeliness; performance of a limited number of joint inspections; and the conduct of common training sessions.

§ 26.16 Suspension.

(a) Each party has the right to contest the equivalence of a regulatory authority. This right will be exercised in an objective and reasoned manner in writing to the other party.

(b) The issue shall be discussed in the Joint Sectoral Committee promptly upon such notification. Where the Joint Sectoral Committee determines that verification of equivalence is required, it may be carried out jointly by the parties in a timely manner, under § 26.6.

(c) Efforts will be made by the Joint Sectoral Committee to reach unanimous consent on the appropriate action. If agreement to suspend is reached in the Joint Sectoral Committee, an authority may be suspended immediately thereafter. If no agreement is reached in the Joint Sectoral Committee, the matter is referred to the Joint Committee as described in § 26.73. If no unanimous consent is reached within 30 days after such notification, the contested authority will be suspended.

(d) Upon the suspension of authority previously listed as equivalent, a party